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EXAMINER	
CHAWLA, JYOTI	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/729,935	NINOMIYA ET AL.	
	Examiner	Art Unit	
	JYOTI CHAWLA	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendments to claims filed December 26, 2007 have been entered. Claims 5 and 6 have been amended, claims 17-29 have been newly added. Claims 1-29 are pending in the application, where claims 1-4 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected product, and remaining claims 5-29 are examined in the application.

Claim Objections

Claims 17-29 are objected to because of the following informalities:
Claim 17, step (iii) recites "filtering the unrefined to remove solids". The term "unrefined" should specify *unrefined soy.* Appropriate correction is required.

Claims 6 and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case the limitation of sodium chloride being less than 5% as recited in claims 6 and 18 is already part of respective independent claims 5 and 17 as amended on 12/26/2007.

Claim Rejections - first paragraph 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejection of claims 5-16 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for not specifying salt concentration that is considered non-inhibiting to the hydrolysis of the protein, has been withdrawn in light of applicant's amendment dated December 26, 2007.

Rejection of claim 16 under 35 U.S.C. 112, first paragraph, has been withdrawn in light of applicant's response dated December 26, 2007, which established the depository is made under the terms of the Budapest Treaty (page 29, foreign priority papers submitted December 9, 2003 contains the deposit receipt). A statement by attorney of record, Mr. Steven Baxter, over his signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, satisfies the deposit requirement (Remarks, Page 9, paragraph 1, filed 12/26/07).

Claim Rejections - second paragraph 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5-29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Rejection of claim 5, step (ii) for being unclear for the amount of salt has been withdrawn in light of applicant's amendments dated December 26, 2007. Also rejection of claims 6 and 9 has been withdrawn in light of applicant's remarks dated 12/26/2007.

Claim 5 is once again rejected along with newly added claim 17 for being unclear as to what is "unrefined soy" and how is the unrefined soy, different from "resulting solid koji". It is unclear whether "unrefined soy" as recited in claims 5 and 17 is "the hydrolysis product of the vegetable protein contained in the resulting solid koji' as stated by the applicant in remarks, page 14, or something else. It is unclear from the claims 5 and 17, as recited, whether soy is the "raw material containing vegetable protein" or is it some other vegetable protein that is part of the "raw material" as recited by the applicant. For the same reasons as above, it is also unclear as to whether soy is part of the "resulting

solid koji" as recited in step (i) of claims 5 and 17. Thus applicant's argument that the claim as recited is clear in its meaning is not convincing and the rejection of claim 5 as being indefinite is maintained for the reasons of record and rejection of newly added claim 17 is being added to how is the unrefined soy, different from "resulting solid koji".

It is also unclear as recited whether " a solution" that is added to the solid koji "at a sodium chloride concentration of 5% by weight" comprises sodium chloride or whether sodium chloride is already present in the solid koji and the solution is of something else. Further, it is also unclear regarding claims 5 and 17, whether the recitation of "a sodium chloride concentration of 5% by weight or less" pertains to the concentration of sodium chloride by weight of the solid koji or the solution or both or something else.

Regarding the rejection of claims 5, 7 and 8 for the term "raw material" being a relative term, which renders the claim indefinite, applicant's remarks on page 15 (step 4) have been considered but have not been found persuasive. Page 11 as cited by the applicant states "The raw materials containing vegetable protein comprise any raw material containing vegetable protein appropriate for foods", further the specification comprises a few examples, which do not represent the entire class of raw materials and also does not include "swelled defatted soybean" as recited in claims 8 and 20. Furthermore, page 16 of the original disclosure states "The resulting unrefined soy is used as *a raw material* for other fermentation seasonings or fermentation food products." Thus the term raw material has not been clearly defined in the original disclosure as alleged by the applicant and rejection of claims 5, 7 and 8 as being unclear for the recitation of a relative term "raw material" is maintained for reasons of record. Further regarding the newly added claims 17, 19 and 20, the claims recite the same relative term "raw material" and are rejected under 35 U.S.C. 112 (second paragraph) for the same reasons of record as stated regarding claims 5, 7, and 8 in the previous office action dated 8/24/2007 and also as discussed above. Thus applicant's arguments are not persuasive, absent any clear and convincing arguments and evidence to the contrary.

Applicant's arguments on page 15 (step 5) regarding claim 10, are not specific. Further the original disclosure "Additionally, the pH of the unrefined soy is adjusted to preferably 4 to 10, more" lacks details as to when and how often during the process of fermentation is the pH adjusted to the recited range of 4-10. Thus claim 10 and the newly added claim 22 are rejected as being indefinite for the recitation of "wherein the unrefined soy in step (ii) is at pH 4-10", as it is still unclear at what part of the step (ii) is the pH of the unrefined soy in the recited range. It is also unclear as to whether the soy is considered unrefined soy before hydrolysis, during or after hydrolysis, or during or after fermentation, or during the entire process. Thus claims 10 and 22 are rejected under 35 U.S.C. 112 (second paragraph).

Claims 11, 12, and new claims 23 and 24 are indefinite for the recitation of "wherein nitrogen of a volume 2- to 10-fold (5 to 8 fold) the volume of the headspace of the fermentation tank is purged to the headspace above the unrefined soy and then the tank is sealed in (ii)." As it is unclear, as recited, whether there is one tank or there are two tanks (one fermentation tank and another in which unrefined soy is kept). Also, as the headspace in the tank or tanks as recited can only be determined by the size of the tank and the batch-size of unrefined soy in the tank, which was not recited in the specification or the rejected claims. Thus specific amount of nitrogen being purged into a tank is not clear for the purposes of prior art comparison. Furthermore, it is unclear whether the fermentation tank is closed with nitrogen atmosphere maintained inside the tank by a closed pipe system or if the fermentation tank is closed after purging with nitrogen once only or any other form of modified atmosphere is maintained in the fermentation tank. Thus the claim as recited in unclear for the purposes of prior art comparison. Applicant's arguments that the claim as recited is clear are not persuasive as the cited parts of page 16, lines 10-14 of original disclosure do not resolve the indefiniteness of the claims as recited as to the fermentation tank and tank containing unrefined soy are the same. Further applicant's original disclosure on page 16, lines 10-14 states that nitrogen purging is done to suppress undesirable microorganisms, however, claims as recited do not clearly recite whether the size of the tank or size of

the unrefined soy in the batch are factors that affect the determination of an amount of nitrogen to be purged to the head space which would be effective in suppressing the proliferation of undesirable microorganisms. Further, as disclosed " As to the degree of nitrogen substitution, for example, nitrogen gas of a volume 2- to 10 fold, preferably 5- to 8 fold the headspace volume of a tank with the unrefined soy is used." (Specification, page 16, lines 12-14). Thus 2-10 folds and 5-8 folds the headspace volume as recited, are examples of the nitrogen volume that would be desirable and not the only values of nitrogen that would be effective in achieving the desired result of suppressing the growth of undesirable microorganisms. Thus applicants' argument that the claims 11 and 12 and the newly added claims 23 and 24 are clearly recited and disclosed in the specification has not been found persuasive and the claims remain rejected for the reasons of record, absent any clear and convincing evidence and or reasons of record.

Claim 23 and 24 are indefinite for the recitation of "wherein nitrogen of a volume 2- to 10-fold (5 to 8 fold) the volume of the headspace of the fermentation tank is purged to the headspace above the unrefined soy and then the tank is sealed in (ii)." Claim 23 recites the limitation "the fermentation tank" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 5, 13 and 14 are indefinite for the recitation of "microorganisms with protein hydrolysis potency". The metes and bounds of the term "protein hydrolysis potency" as recited are unclear. Applicant's argument that the claim as recited is clear based on the disclosure of page 11, lines 12-19, however the original disclosure gives a generic definition and examples of organisms that have ability to breakdown or hydrolyze protein by way of enzymes. Thus as disclosed it is not clear whether the term "microorganisms *with* protein hydrolysis potency" refers to the external enzymes such as hydrolases, proteases, peptidases etc., or to the microorganisms which are added to koji have protein hydrolysis potency (i.e., ability of breaking down proteins) or both. Newly added claims 17, 25 and 26 recite same limitations as discussed regarding claims 5, 13 and 14 and thus are rejected for the same reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Determining the scope and contents of the prior art.
Ascertaining the differences between the prior art and the claims at issue.
Resolving the level of ordinary skill in the pertinent art.
Considering objective evidence present in the application indicating obviousness or nonobviousness.

(A) Claims 5-7, 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baensch et al (US 5965178) in view of Takebe et al (US6303161 B1).
References and rejection are incorporated herein and as cited in the office action dated August 24, 2007.

Regarding the amendment to claims 5 and 6, as to the concentration of sodium chloride being less than 5%, applicant is referred to Baensch (Abstract, Column 2, lines 8-10, Column 3, lines 1-5), where Baensch teaches that the vegetable protein based fermented seasoning can be made in the absence of salt in the soy during or before hydrolysis (i.e., step (ii)). Regarding the nature of salt, Baensch also refers to salt as common salt (lines 20-25), which is the commonly used term for sodium chloride. Thus the reference teaches of no addition of sodium chloride, which falls within the concentration as instantly claimed by the applicant.

(B) Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baensch in view of Takebe , as applied to claims 1-7 and 9-16 above, and further in view of Arnaud et al (US 3917851).
References and rejection are incorporated herein and as cited in the office action dated August 24, 2007.

(C) Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baensch in view of Takebe , as applied to claims 1-7 and 9-16 above, and further in view of Izumi (US 4008333).
References and rejection are incorporated herein and as cited in the office action dated August 24, 2007.

(D) Claims 17-19 and 21-22, 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baensch et al (US 5965178) in view of the combination of Takebe et al (US6303161 B1) and Marumoto et al (US 3690900).

Regarding claim 17-19, 21-29, Baensch et al hereinafter Baensch, teaches a seasoning composition and method of making the seasoning fermentation of plant based protein material (Column 2, lines 55-62) as instantly claimed. The reference teaches of a process of producing the seasoning comprising:
(i) preparing koji is fermented in the solid state (i.e., solid koji) by inoculating koji mold on vegetable protein source to make koji (Column 2, lines 50-67). Koji mold taught by the reference includes Aspergillus, such as Aspergillus oryzae, and Aspergillus sojae (Column 2, lines 50-67), which are the same filamentous fungi as recited by the applicant in claims 13 and 14. Since the reference teaches of the same fungus as recited by the applicant therefore the reference also teaches of a microorganism having the protein hydrolysis potency to hydrolyze the vegetable proteins present in the raw materials (vegetable protein material) as instantly claimed.

Regarding step (ii) Baensch teaches of hydrolysis of the fermented solid protein koji in the presence of water with or without the addition of salt (Column 3, lines 1-3), thus the reference teaches of fermenting the koji obtained from the first fermentation of step (i.e., step (i) as recited) and hydrolyzing the protein in a solution with or without salt in a solution that does not inhibit the hydrolysis of the protein to form unrefined soy and then fermenting the unrefined soy.

Regarding the hydrolysis ratio of the seasoning, Baensch teaches of using soybeans as the source of the vegetable proteins (Column 2, lines 57). Baensch also teaches that the soybean is cooked (Column 2, lines 59-60). The reference does not specify the amino acid percent after hydrolysis as instantly claimed. It was known at the time of the invention that cooking of soy beans increases the digestibility of protein by the enzymes from 65-90%, as taught by Wiley's encyclopedia of food Science and technology, (Page 2178), which falls in the applicant's recited range. Baensch teaches of cooking the soybeans as discussed above and cooking the beans or soybean meal increases the protein digestibility to 65-90% or in other words cooking as taught by Baensch, increases the hydrolysis of proteins to form constituent amino acids in the ratio of 65-90%, which falls in the instantly claimed range. Regarding the concentration of isobutyl alcohol, n-butyl alcohol; isoamyl alcohol; and acetic acid, the reference teaches of making a vegetable protein based seasoning/spice/health product by the addition of Aspergillus and lactic acid bacteria (as instantly claimed) by a two-step fermentation process as recited, in the time, temperature and pH in the recited range of the applicant. Since the reference teaches of similar process as instantly claimed, one would expect that the product as produced by the method as taught by modified Baensch would have similar characteristics to the product as instantly claimed (i.e., a similar concentration of isobutyl alcohol, n-butyl alcohol; isoamyl alcohol; and acetic acid to the instantly claimed product), absent any clear and convincing evidence and arguments to the contrary. Regarding the addition of lactic acid bacteria twice to the fermentation mixture once during the fermentation step to make solid koji and secondly during or just before the

hydrolysis step, Baensch teaches of the addition of lactic acid bacteria to either in the koji step or during the hydrolysis step (Abstract). The reference further teaches that

1. when the inoculation with a culture of lactic acid bacterium is carried out in the fermented koji stage, the inoculation may take place
   - before,
   - at the beginning,
   - anytime during the fermentation process (Column 2, lines 60-67).
2. when the inoculation is carried out at the hydrolysis stage, the inoculation may take place
   - before,
   - at the beginning,
   - anytime during the hydrolysis process (Column 3, lines 10-14).

Thus Baensch teaches that the lactic acid bacteria can be added either during step (i) or during step (ii) in such a way that the hydrolysis of the proteins can take place in the presence of lactic acid bacteria. The reference is silent to the addition of lactic acid bacteria in both the steps.

Takebe teaches of making soy based fermented health product (by soy sauce fermentation process), where the reference teaches of the addition of lactic acid bacterium as intestine regulating bacterial culture to the vegetable protein soybeans. Lactic acid bacteria are added at the same time as the inoculation of the koji and the period of growth of lactic acid bacteria extends from the period of inoculation of the koji mold to the completion of hydrolysis. Lactic acid bacteria have a good compatibility with the koji mold. The bacteria also propagate well without interfering with the growth of koji mold. Furthermore, addition of lactic acid bacteria at the same time as the addition of the koji mold (i.e., instantly claimed step (i)), enhances the production efficiency of the koji (Column 6, lines 10-51). Takebe further teaches that the lactic acid bacterial population is sustained to the completion of the hydrolysis (i.e., instantly claimed step (ii)) (Column 6, lines 20-51). Thus the reference teaches that the lactic acid bacteria are inoculated along with the koji mold and cultivated during the entire process as is instantly claimed.

Based on the above discussion, the three references teach the following:

- Methods of making fermented seasoning/spice/ hydrolyzed protein/healthful products from vegetable protein source (soy) by the addition of lactic acid bacteria and koji fungus (Aspergillus oryzae, Aspergillus sojae) were known in the art at the time of the invention as taught by Baensch and Takebe.
- Process of making a fermented vegetable protein based seasoning where lactic acid bacteria can either be added to the vegetable protein at the time of koji preparation (i.e. step (i)) or at the time of hydrolysis of the fermented koji (i.e. step (ii)) was also known at the time of the invention (Baensch).
- An effective population of lactic acid bacteria in the fermentation mixture at the time of koji preparation and also at the time of protein hydrolysis provides the benefit of higher degree of release of amino acids in the final product than produced by conventional soy sauce processes when the hydrolysis takes place in the presence of lactic acid bacteria (Baensch, Column 2, lines 30-35, Column 3, lines 60-62).
- Addition of lactic acid bacteria at the time of the inoculation of koji fungus during the time of koji preparation process (i.e., step (i)) was known to increase the efficiency of production because the lactic acid bacteria are compatible with the koji fungus and do not interfere in the growth of the fungus (Takebe).
- Hydrolysis of vegetable proteins takes place faster in the presence of an effective amount of lactic acid bacteria.
- Effective amount of bacteria in the fermentation mixture depends upon various factors, such as, pH (salt concentration), temperature, nutrients, the availability, viability or initial concentration of inoculum and the time period allotted for the bacterial and fungal cultures to grow and ferment the substrates.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Baensch such that lactic acid bacteria are added at either the koji preparation stage (Baensch or Takebe) or during the protein hydrolysis stage (Baensch)

or during both steps during the process of making a fermented vegetable protein based seasoning. One would have been motivated to add the lactic acid bacteria more than once during the making of the seasoning in order to have an effective population of lactic acid bacteria in the fermentation mixture at the time of koji preparation and also at the time of protein hydrolysis to make a product with higher degree of release of amino acids in the final product than produced by conventional soy sauce processes when the hydrolysis takes place in the presence of lactic acid bacteria (Baensch, Column 2, lines 30-35, Column 3, lines 60-62). One would have been further motivated to add the lactic acid bacteria to the fermentation mixture in at least a single step or more, depending upon various factors of the fermentation media, such as, the pH (salt concentration), temperature, nutrients etc. One would have also been motivated to add the lactic acid bacteria more than once during the process based on the availability of inoculum, initial concentration or viability of the inoculum. Further the time period required by the bacterial and fungal cultures to ferment the substrates and hydrolyze the proteins would also influence the decision to add the lactic acid bacterial culture once or more times during the process of making a fermented vegetable protein based seasoning/ spice/ healthful product.

Regarding the amount of bacteria added the Baensch reference teaches that the amount of lactic acid bacteria added either at the time of the koji preparation or during the time of hydrolysis in the amount of 10^3 to 10^7 CFU per gram. The concentration of the added bacterial inoculum is less than the recited bacterial concentration of 10^8 to 10^{11} cells per gram. Takebe teaches of addition of an inoculum of 10^3 CFU per gram, which is smaller than the one recited in the claim, however the reference teaches that the bacterial population grows to 1.7 X 10^7 CFU per gram during the preparation of koji and increases to between 2.2 X10^9 to 3.4 X10^9, which falls within the recited range of the applicant. Thus the effective bacterial population in the seasoning within the recited range of the applicant was known at the time of the invention. Therefore, it would have been well within the purview of one of ordinary skill in the art to

- either add more bacteria to the culture medium and maintain the bacterial population or
- to add a rapidly multiplying bacterial strain and provide conditions for rapid increase in the population of bacteria in the vegetable protein culture medium based on the strain of bacteria, availability and cost constraints at the time.

Thus to alter the bacterial strain, inoculum concentration or the culture medium to grow and sustain the bacterial population in the vegetable protein based culture medium as taught by Takebe, would have been well within the purview of one of ordinary skill in the art at the time of the invention. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the amount of lactic acid bacteria either during the preparation of koji step or during the hydrolysis step or both, in order to have an effective amount of the bacterial population along with an effective population of koji fungus in the fermentation mixture to make good koji containing intestine regulating lactic acid bacterial culture. One would have been motivated to modify the amount of bacteria added to the koji or hydrolysis solution as taught by Baensch, based on the nature of lactic acid bacteria (i.e., the strain of lactic acid bacteria chosen), the concentration of solutes, such as, salt in the fermenting mixture (Column 3, lines 1-10). One would have been also motivated to add the higher concentration of lactic acid producing bacterial culture in order to make the soy based fermented seasoning product as taught by Baensch, in a shorter period of time. One would have been further motivated to modify the amount of lactic acid bacteria based on the pH of the culture medium, availability of bacterial innoculum and viability of the bacterial sample available at the time of the invention. Addition of a larger or smaller concentration of bacteria to a fermentation broth in order modify the speed of fermentation would not provide patentable distinction to the claims as recited, absent any clear and convincing evidence and arguments to the contrary.

Regarding step (iii) of claim 17, Baensch teaches of removing the solids from the liquid seasoning by pressing and then pasteurizing and then filtering the liquid soy based seasoning (Column 3, lines 50-58). Thus Baensch recognizes the problem of separation

of solids from the liquid seasoning (unrefined soy) and teaches of pressing and filtering as two steps for the separation of solid matter from the soy product. Therefore Baensch teaches of filtering the unrefined soy as recited by the applicant.

Regarding step (iv) of claim 17, Baensch teaches of pasteurizing the liquid soy based seasoning (Column 3, lines 50-58), after the separation of solids, Baensch teaches of pasteurizing the soy based seasoning product (recited as unrefined soy). Baensch teaches of pasteurization at a temperature range of 60-120 ^{0}C for 1-60 minutes (Column 3, lines 50-58), which is also the temperature range of the sterilization treatment recited by the applicant in claim 29. Thus Baensch teaches heat treatment of the fermented seasoning in the recited temperature range of the applicant. Pasteurization and sterilization are both heat treatment methods employed to kill the naturally occurring bacteria and were known in the art of making soy based fermented seasoning at the time of the invention. Pasteurization is a method of treating liquids for the purpose of reducing the microbial population in food products to within safe limits for human consumption, while sterilization is a more severe method where the process effectively kills or eliminates transmissible agents in the food. Baensch teaches pasteurization of the fermented soy seasoning and Marumoto et al , hereinafter Marumoto teaches of sterilizing the soy sauce (Column 8, lines 25-30, Example 8). Thus both the heat treatment methods were known and used effectively to reduce the microbial population of foods at the time of the invention.

- Filtration as a method of separating solids from liquid seasoning was known at the time of the invention.
- Heat treatment of the finished product at a temperature range of 60-120 ^{0}C for 1-60 minutes (Baensch Column 3, lines 50-58) was known at the time of the invention. Temperature of the heat treatment as taught by Baensch is the same as the temperature range disclosed by the applicant regarding sterilization heat treatment (Specification, page 16, lines 18-22 and claim 29).

- Sterilization as the form of heat treatment for fermented soy based seasonings was also known at the time of the invention (Marumoto, Column 8).

Therefore, it would have been obvious to one of ordinary skill to modify Baensch based on the teaching of Marumoto and sterilize the soy based seasoning, in order to make a finished product where all of the harmful bacteria as well as the beneficial lactic acid bacteria are effectively killed. One would have been motivated to do so in order to make a liquid or solid fermented soy seasoning product that can be stored and saved for a relatively longer period of time as compared to a liquid product that has either been pasteurized or is untreated.

Regarding the order of filtration and sterilization Baensch teaches of heat treatment (pasteurization) before filtration, however, to modify the sequence of steps and filter the seasoning product prior to heat treatment or vice versa can be changed based on the desire of one of ordinary skill in the art and the efficiency of making the product, e.g., if the liquid product is packaged for shipping, then filtering, packing and subsequent heat treatment is more desirable. However, if the intended purpose is to effectively stop the fermentation and hydrolysis of the seasoning product and seasoning product is to be processed further, then heat treatment can be done prior to filtration of the seasoning product. Thus, it would have been a matter of routine determination for one of ordinary skill at the time of the invention to vary the sequence of events as desired, in order to make the finished product in most effective and efficient way, and changing the sequence of steps would not lend patentable distinction to the claim as recited, absent any clear and convincing evidence and arguments to the contrary.

NOTE: Regarding the above limitation to claim 17, applicant is further referred to the rejection under 35USC 112 above.

Regarding claim 18, Baensch teaches that the vegetable protein based fermented seasoning can be made with or without salt to the soy during or before hydrolysis (i.e.,

step (ii))(Abstract, Column 2, lines 8-10, Column 3, lines 1-5). Thus the reference teaches of salt concentration in the unrefined soy as instantly claimed.

Regarding claim 19, Baensch teaches that the raw material containing vegetable protein is soybean (Column 2, lines 57). The reference also teaches that defatted soy was used to make seasonings like soy sauce at the time of the invention (Column 1, lines 16-17). Thus the reference teaches that defatted soybean can be used to make the seasoning as instantly claimed.

Regarding claim 21, Baensch teaches that the hydrolysis step is carried out after the addition of water (i.e., step (ii) as recited) is carried out preferably at 30-45^0 C or 2-20^0 C for a period of 12 hours to 25 days which includes the instantly claimed range of time (Column 3, lines 17-28, also see Column 2, lines 15-22). Thus the reference teaches of hydrolysis time and temperature in the range recited by the applicant.

Regarding claim 22, Baensch teaches, wherein the unrefined soy in (ii) is at pH 4.5 to 10 (Column 2, lines 28-30) as instantly claimed.

Regarding claim 25 and 26, Baensch teaches of filamentous fungi that belong to the genus Aspergillus and specifically from the group consisting of Aspergillus oryzae and Aspergillus sojae (Column 2, lines 53-54), as instantly claimed.

Regarding claim 27, Baensch teaches that the lactic acid bacterium can be a lactic acid bacterium (Column 2, lines 18-20). The reference further teaches that non-limiting examples of lactic acid bacteria which may be used include Lactobacillus sake (L. sake), L. crispatus, L. gasseri, L. johnsonii, L. reuteri, L. rhamnosus, L. curvatus, L. plantarum, L. helveticus, L. paracasei, L. fermentum, L. alimentarius, L. brevis, L. delbrueckii, L. farciminis, L. acidophilus and other Lactobacillus species, Leuconostoc mesenteroides, Pediococcus pentosaceus, Pediococcus acidilactici, Streptococcus thermophilus, Enterococcus faecalis, Enterococcus faecium and Tetragenococcus

halophilus, etc. These organisms may also be used as mixtures of different strains, which may comprise different (two or more) species (Column 2, lines 38-50). Thus the reference teaches of lactic acid bacteria of genus Lactobacillus. Regarding the Lactobacillus lactis, Takebe teaches of addition of lactobacillus lactis and koji fungus to ferment a soy-based product (Column 10, line 61), as is instantly claimed. Thus addition of Lactobacillus as lactic acid bacteria to koji in order to make soy based fermented seasoning was known in the art (Baensch, Column 2, lines 38-50). Addition of Lactobacillus lactis bacteria along with koji fungus to make koji was also known in the art at the time of the invention. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Baensch and add Lactobacillus lactis as the lactic acid bacteria to ferment koji and hydrolyze proteins. One would have been motivated to add lactobacillus lactis in order to have an easily available and affordable bacterium that has an intestine regulating function as taught by Takebe.

Regarding claim 28, Baensch in view of Takebe teaches that the lactic acid bacterium is Lactococcus lactis (Takebe, Column 10, line 61), however the references do not teach the specific subspecies or strain of the bacterium as recited by the applicant (L. lactis FERM BP-08552). Regarding the reference not disclosing the specific Lactobacillus lactis FERM BP-08552 as is instantly claimed, it is noted that although the bacterial strain as taught by the references Baensch and Takebe is not the same as is recited, however the bacteria taught by Baensch and Takebe are also lactic acid producing bacteria as instantly claimed in claims 5, 15 and 16. The lactic acid bacteria taught by Baensch and Takebe have the following characteristics in common with the claimed enzymatically effective agent as recited:

- Takebe teaches the same genus and species of bacteria (Lactobacillus lactis) as instantly claimed,
- Baensch and Takebe teach addition of the lactobacillus (lactic acid bacteria) in addition to Aspergillus fungus to the soy based substrate to produce koji and soy hydrolysate as is instantly claimed.

- The applicant has not claimed a specific enzyme or enzymatically effective agent or any unexpected result that can be obtained specifically from addition of subspecies L. lactis FERM BP-08552 which can not be obtained from other lactic acid producing bacteria including other lactobacilli as taught by Baensch or L.lactis species as taught by Takebe.

Therefore, the L. lactis FERM BP-08552, as recited by the applicant would appear to be the same taught by Baensch in view of Takebe. Furthermore, even if the enzymatically effective agent is not exactly the same as the one obtained from other lactic acid bacteria including other L. lactis, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute one art recognized functional equivalent (i.e. L. lactis as taught by Takebe) for another (L. lactis FERM BP-08552 as instantly claimed) in hydrolyzing the soybean koji by the method as taught by Baensch, depending on which strain of L.lactis or lactic acid bacterium was more easily available and affordable at the time the invention was made, absent any clear and convincing evidence and arguments to the contrary.

(E) Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baensch in view of the combination of Takebe and Marumoto above, and further in view of Arnaud et al (US 3917851).

Baensch in view of Takebe and Marumoto, has been applied to claims 17-19, 21-22, and 25-29 above as discussed above.

Regarding claim 20, Baensch teaches of cooking the soybeans and used in solid particulate form (Column 2, lines 59-62). Takebe also teaches of modifying and swelling soybean. The references do teach of the particulate form, however, Baensch does not specifically state extrusion cooking as the method of cooking soy. However extrusion cooking of defatted soy was known in the art at the time of the invention as taught by Arnaud et al, hereinafter Arnaud. Arnaud teaches of extrusion cooking of defatted soy for making fermented soy based product (column 2, lines 15-18 and 25-33). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Baensch and cook the soybean by extrusion cooking method in order to make

the protein and carbohydrates of the bean readily available for microbial action. One would have been motivated to use extrusion cooking as the method of cooking the soybean as extrusion cooking is fast and it shortens the processing time for preparation of soybean before inoculation with koji fungus and lactic acid bacteria as instantly claimed.
Regarding the nitrogen solution index (NSI) for the soybean of 8 to 20, it was known in the art at the time of the invention that NSI of cooked soy product typically a flour, with an NSI of about 20 to 60. Since the Baensch reference teaches of a cooked soybean particulate, it would be obvious to one of ordinary skill in the art at the time of the invention that the soy material taught by Baensch would have the NSI characteristics in the range as instantly claimed by the applicant absent any clear and convincing evidence and arguments to the contrary.

(F) Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baensch in view of the combination of Takebe and Marumoto above, and further in view of Izumi (US 4008333).
Baensch in view of Takebe and Marumoto, has been applied to claims 17-19, 21-22, and 25-29 above as discussed above.
Regarding claims 23 and 24, Baensch teaches of method of making a fermented soy based seasoning composition, which utilizes koji fungus and lactic acid bacteria to ferment the soy based substrate. The reference teaches of hydrolysis of proteins where the fermentation may be done either in a single step or in two steps (step (ii) as instantly claimed). The reference is silent as to whether the hydrolysis takes place anaerobically or without the presence of oxygen. The reference is also silent about an inert gas replacing the headspace in the fermentation tank. However methods of making fermented soy based seasoning, where the hydrolysis (i.e., step (ii) as recited) takes place in a modified atmosphere in a closed fermentation vessel were known at the time of the invention. Izumi teaches of a method of making soy based seasoning where the fermentation of soy sauce takes place in large batches in a closed type tank in order to reduce the fermentation time of the soy based seasoning (abstract and Column 2).

Izumi reference teaches that the moromi (i.e., unrefined soy or soy koji with water after the koji formation step) when ferments includes carbon dioxide, which needs to be removed from the fermenting moromi in order to speed up the fermentation process. The removal of carbon dioxide is done by providing a ventilation gas which can be oxygen including gas, such as air or an inert gas (i.e., a gas that is inactive to the unrefined soy or moromi (Column 3, line 25 to Column 4, line 7). The reference further teaches that excess of oxygen oxidizes the unrefined soy and deteriorates the quality of the finished product, thus inert gas atmosphere is preferred. Izumi also teaches of nitrogen as the preferred inert gas (Column 4, lines 4-7). Regarding the amount of nitrogen in the tank, Izumi teaches that the feeding rate of the inert gas may be varied in accordance with the raw material of moromi, temperature of fermentation etc., in the fermentation tank (Column 4, lines 8-13). The reference further teaches that for a 1000-liter fermentation tank, the volume of inert gas circulated is 700-1500 liter per hour (column 4, lines 10-21). In an example the reference teaches that 167-ton of water and 12 ton of koji along with 250 Kg (i.e., 0.25 ton) of malt in a 200 Kiloliter tank (Column 7, lines 18-20). It is noted that 1 ton is approximately equal to 1.132 kiloliters, thus by that conversion 167 tons of water =167 X1.1 =184 Kiloliter capacity
Assuming that koji and malt occupy very little space and weigh negligible then the percent of occupied volume in the tank would be about 92% (i.e., [(184/200) X100=92]). Thus the volume of the fermentation tank headspace would fall in the range of about 8% in case of the example, based on the discussion above. Thus the reference teaches that the headspace of the closed fermentation tank is in the range of about 8%, which would be considered to be 10% for the ease of calculation. The reference also teaches of volume of nitrogen can be varied and that the volume is generally 0.7 to 1.5 times the total volume of the fermentation tank as discussed above (column 4, lines 10-21). Therefore, based on the above information the volume of nitrogen purged into the fermentation tank in a closed type fermentation system is about 7-15 times the headspace, which includes applicant's recited range in claims 23 and 24 as instantly claimed. Thus introducing an inert gas, such as nitrogen, in a closed type fermentation system (as instantly claimed), in the volume range recited by the applicant was known

at the time of the invention. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify Baensch in view of Izumi and flush the fermentation tank/ vessel with nitrogen in the volume ratio as taught by Izumi in order to remove the carbon dioxide without introducing excessive amounts of oxygen in order to shorten the brewing period of soy based seasoning without compromising the quality of the finished product as taught by Izumi (Column 3, lines 25 to Column 4, line 53).

NOTE: Regarding the above limitation of the volume of nitrogen in relation to the headspace as recited in claims 23 and 24, applicant is further referred to the rejection under 35USC 112 above.

Response to Arguments

Applicant's arguments filed December 26, 2007 have been fully considered but they are not persuasive.

In the instant case the applicant alleges that Baensch fails "to disclose addition of lactic acid bacteria during step (i) and (ii) (b) failure to disclose the concentration of the lactic acid bacteria present during either step (i) or (ii); (c) failure to disclose the hydrolysis ratio of the seasoning; and (d) failure to disclose the concentration of isobutyl alcohol, n-butyl alcohol, isoamyl alcohol, and/or acetic acid in the seasoning" and "Takebe does not (Remarks, page 9). In response to applicant's arguments against the references individually, applicant is reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller,* 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.)

Applicant's argument that Baensch differs from the instantly claimed invention on several accounts, however, applicant is reminded that claims 5-29 are not anticipated by Baensch but are obvious over Baensch in view of combination of references including Takebe, Marumoto, Izumi and Arnaud, as discussed in the office action dated 8/24/07 and also as discussed above regarding claims 17-29.

In response to applicant's argument that Baensch does not teach the addition o lactic acid bacteria during step (i) and step (ii), applicant is referred to the rejection where Baensch in view of Takebe teach the addition of lactic acid producing bacteria more than once during the preparation of fermented soy based seasoning. The applicant is further referred to rejection of claim 17 above (also see page 15 of the original disclosure), where it has been discussed that addition of lactic acid bacteria during various steps in the fermentation and hydrolysis process to make a seasoning product was known at the time of the invention. Further

- Lactic acid bacteria were known to work synergistically with the koji mold in order to make a benefit of higher degree of release of amino acids in the final product than produced by conventional soy sauce processes when the hydrolysis takes place in the presence of lactic acid bacteria (Baensch, Column 2, lines 30-35, Column 3, lines 60-62).
- Addition of lactic acid bacteria at the time of the inoculation of koji fungus during the time of koji preparation process (i.e., step (i)) was known to increase the efficiency of production because the lactic acid bacteria are compatible with the koji fungus and do not interfere in the growth of the fungus (Takebe).
- Hydrolysis of vegetable proteins takes place faster in the presence of an effective amount of lactic acid bacteria.

Thus the decision to add lactic acid bacteria to the fermentation broth in one or more steps would have been a matter of routine determination and optimization experimentation for one of ordinary skill in the art at the time of the invention. Therefore, addition of lactic acid bacteria more than once for their known benefit of increasing digestibility of the vegetable protein and shorter preparation time for the fermented seasoning, would have been obvious to one of ordinary skill at the time of the invention, absent any clear and convincing evidence and/ or arguments to the contrary.

Applicant's argument that Baensch in view of Takebe fail to provide the concentrations of isobutyl alcohol etc as recited in claims 5 and 17 (Remarks, page 12), has not been

found persuasive as the applicant has merely alleged but has shown no evidence that the isobutyl alcohol, n-butyl alcohol and acetic acid are not inherently present in the seasoning as taught by Baensch in view of Takebe.

Applicant's arguments regarding the rejections under 35 U.S.C. 112 (second paragraph) have been responded in the office action above.

Therefore, applicant's remarks filed 12/26/2007 have been fully considered but have not been found persuasive and claims 5-29 remain rejected for reasons of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI CHAWLA whose telephone number is (571)272-8212. The examiner can normally be reached on 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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